UNITED STATES DISTRICT COURT
IN THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

BRENDA CRISP,
Plaintiff,

vs. Case No.
Hon.

JOHNSON & JOHNSON,
a New Jersey corporation;
ETHICON, INC. a New Jersey corporation;
ETHICON ENDO-SURGERY, an Ohio corporation;
ETHICON US, LLC, a Texas limited liability company;
AND JANE AND JOHN DOES 1-20.
Defendants.
_____/

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COMPLAINT AND JURY DEMAND

NOW COMES PLAINTIFF, BRENDA CRISP, by and through her counsel OLIVER LAW GROUP PC, and in support of her Complaint and Jury Demand states as follows:

Introduction

1. This is a product liability case involving a defective a stapler produced and sold by Ethicon Defendants described as a stapler, internal, 2.5 MM STD Curved with product identification of ECS25A (hereinafter "EEA" or "EEA device") produced by Defendants that was used in the course of Plaintiff's abdominal surgery of April 12, 2019, in Wayne County, Michigan. As a direct result of defective nature of the stapler, Plaintiff was injured as more fully set forth herein.

Parties, Jurisdiction, and Venue

2. Plaintiff is and was, at all times relevant to the events complained of herein, a resident of the County of Wayne, State of Michigan.
3. The EEA device was utilized on Plaintiff on April 12, 2019, in the County of Wayne, State of Michigan.
4. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation headquartered in New Jersey. In 1947 it acquired a company that it renamed Ethicon Suture Laboratories. In 1953, this became Defendant Ethicon, Inc. ("Ethicon"). Defendant Ethicon, Inc. is a New Jersey Corporation headquartered in New Jersey. In 1992 Ethicon was restructured and Defendant Ethicon Endo-Surgery, Inc. ("Ethicon Endo -Surgery") became a separated Ohio Corporation headquartered in Cincinnati, Ohio. In 2013, J&J merged Ethicon Endo-Surgery back into Ethicon. Ethicon Endo-Surgery is now a subsidiary of Ethicon, Inc.,

which is a subsidiary of J&J which has no parent company. Ethicon, US LLC is a business organized under the laws of the State of Texas and wholly owned subsidiarity of Johnson & Johnson. These defendants are collectively referred to as the "Ethicon Defendants"

5. Upon information and belief, the Ethicon Defendants are, and, at all relevant times, were, engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, supplying, selling, marketing and/or introducing in interstate commerce, including in the State of Michigan, either directly or indirectly through third parties or related entities, its products, including the Ethicon Stapler that was used to perform the anastomosis in Plaintiff's surgery.
6. At all relevant times, the Ethicon Defendants manufactured, marketed, and sold a product called the Ethicon Surgical Stapler, including the EEA device referenced above and utilized during Ms. Crisp's April 12, 2019, surgery.
7. Upon information and belief, J&J participated in, controlled, knew about, and approved the other Ethicon Defendant's conduct in the development, design, sales, and marketing of the Ethicon Stapler. Defendant Ethicon and Ethicon US, LLC, controlled, knew about, and approved of, Ethicon Endo-surgery's conduct in the development, design, sales, and marketing of the Ethicon Stapler. Defendants Ethicon and Ethicon US, LLC are liable for the tortious conduct of

Defendant Ethicon Endo-Surgery. Defendant J&J is liable for the tortious conduct of all other Ethicon Defendants.

8. The Court has personal jurisdiction over the Ethicon Defendants because the Ethicon Defendants, individually and/or acting in concert, presently and during the time of Plaintiff's surgery regularly did business in the State of Michigan such that they reasonably would expect to have to defend themselves in a Michigan court.

9. Given the grave injuries sustained by Ms. Crisp as outlined herein, the amount in controversy exceeds $75,000.00.

Facts

10. Plaintiff reincorporates the foregoing paragraphs as if full restated herein.

11. On April 12, 2019, Ms. Crisp was a 72-year-old female with a history of COPD, hypertension, and colovaginal fistula.

12. On that date, Ms. Crisp presented for surgery at Beaumont Hospital – Trenton for resection of her sigmoid colon related to the colovaginal fistula, having previously undergone placement of preoperative ureteral stents.

13. After her April 12, 2019 surgery, Ms. Crisp was initially extubated but required reintubation due to episodes of desaturation. She was transferred to Surgical ICU on a mechanical ventilator with a wound vacuum and left abdomen drain. While

there, she was treated for shock, acute respiratory failure, lactic acidosis, acute blood loss anemia, and hyponatremia.

14. On April 19, 2019, Ms. Crisp underwent removal of the preoperative ureteral stents under anesthesia.

15. Subsequently, Ms. Crisp developed increasing abdominal discomfort, change in drain output, and a CT scan identified fluid collection along the left lateral border with possible abscess and possible air within it.

16. On April 23, 2020, Dr. Beaudry performed an exploratory laparotomy under anesthesia. During this exploratory laparotomy, a hole or rent approximately 3 to 4 centimeters in size along the left anterior aspect of the anastomotic site was found. It was found to be irreparable, and the decision was then made to staple the rectum closed and create an end colostomy.

17. Over the course of hospitalization, Ms. Crisp received total transfusion of 7 units of blood and required antibiotics for treatment of this pelvic abscess that was eventually switched over to oral antibiotics. Her pathology report was consistent with acute abscess at initial surgery and abscess formation following EEA leak.

18. Ms. Crisp was then discharged to rehab. Thereafter and continuing to date, Ms. Crisp has suffered ongoing health problems, complications and concerns from her April 12, 2019 surgery that utilized the recalled EEA device resulting in a

signature injury from the defective product, and suffered permanent loss of an important bodily function.

19. During the course of the April 12, 2019, surgery, a stapler was utilized, specifically, a stapler produced and sold by Ethicon Defendants described as a stapler, internal, 2.5 MM STD Curved with product identification of ECS25A.

20. On March 8, 2019, the FDA had warned health care providers about problems with the EEA device including 366 deaths, over 9,000 serious injuries, and over 32,000 malfunctions. **Exhibit A**.

21. The device was recalled via initiation of notice by Ethicon Defendant(s) to the FDA on April 11, 2019, because uncut washers in the stapler and malformed staples occur due to insufficient firing which can compromise staple line integrity. **Exhibit B.**

22. The FDA notice indicates: "an investigation of the manufacturing process detected a shift in a process, which occurred in March and continued through March 8, 2019, at which time the line was shut down". **Exhibit B.**

23. The recall was classified as a Class I recall within the FDA, which is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. **Exhibit C**.

24. Prior to the recall, Ethicon Defendants had received actual knowledge that the product was defective and that there was a substantial likelihood that the defect

would cause the injury; but nevertheless willfully disregarded the knowledge in the manufacture and/or distribution of the EEA.

25. In addition, the EEA device itself was classified as a Class I device within the FDA, which are considered low-risk devices. Examples include bandages, handheld surgical instruments and non-electric wheelchairs. As such, the EEA used on Ms. Crisp was exempt from review by the FDA and did not have FDA premarket approval. **Exhibit D.**

26. Only thereafter have efforts been made to reclassify EEA's such as the one utilized in Plaintiff's surgery to require FDA approval. **Exhibit E.**

COUNT 1 – PRODUCTS LIAIBLITY: GROSS NEGLIGENCE and NEGLIGENCE

27. Plaintiff incorporates the preceding allegations as if fully incorporated herein.

28. At all times relevant, Ethicon Defendants owed a duty to Plaintiff and the public in general to:

a) Properly manufacture its EEA device utilized on Plaintiff;

b) Properly test its EEA device utilized on Plaintiff;

c) Properly sell its EEA device utilized on Plaintiff;

d) Purchase its products from reputable manufacturers or properly test the products it sells;

e) Timely discover processes involved in the manufacturing process that deviate from the FDA approval of the product;[1]

f) Manufacture the EEA device utilized on Plaintiff in conformity with its FDA approval;[2] and

g) Timely alert purchasers of substantial adverse events related to its EEA device and timely initiate market recalls.

29. Ethicon Defendants breached these duties by committing or omitting the following acts:

i. Failing to properly manufacture its EEA device utilized on Plaintiff;

ii. Failing to properly test its EEA device utilized on Plaintiff;

iii. Failing to properly sell its EEA device utilized on Plaintiff ;

iv. Failing to purchase its products from reputable manufacturers or properly test the products it sells;

[1] Plaintiff pleads this in the alternative; it is Plaintiff's primary position that the EEA device was exempt from FDA approval and that Plaintiff need not show deviation from FDA approved manufacturing process.

[2] Plaintiff pleads this in the alternative; it is Plaintiff's primary position that the EEA device was exempt from FDA approval and that Plaintiff need not show deviation from FDA approved manufacturing process

v. Failing to timely discover processes involved in the manufacturing process that deviate from the FDA approval of the product;

vi. Failing to manufacture the EEA utilized on Plaintiff in conformity with its FDA approval; and

vii. Failing to timely alert purchasers of substantial adverse events related to its EEA device and timely initiate market recalls.

30. The product was not reasonably safe when it left the control of Ethicon Defendants.

31. When the product left the control of the Ethicon Defendants, a technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others.

32. In addition, Ethicon Defendants were required to comply with administrative regulatory standards regarding the manufacturing, testing and sales of the EEA device including:

1. 21 CFR 820 is applicable to the Ethicon Defendants and the EEA device. The requirements of 21 CFR 820 include:

a. "Each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part." 21 CFR 820.5.

b. "Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications." 21 CFR 820.70(a).

c. "Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action." 21 CFR 820.100(a). These are referred to as "CAPA" procedures.

d. The CAPA procedures must include requirements for: "Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems." 21 CFR 820.100(a)(1).

e. The CAPA procedures must include requirements for: "Investigating the cause of nonconformities relating to product, processes, and the quality system[.]" 21 CFR 820.100(a)(2).

f. The CAPA procedures must include requirements for: "Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems[.]" 21 CFR 820.100(a)(3).

g. The CAPA procedures must include requirements for: "Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device[.]" 21 CFR 820.100(a)(4).

h. The CAPA procedures must include requirements for: "Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems[.]" 21 CFR 820.100(a)(5).

i. The CAPA procedures must include requirements for: "Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems[.]" 21 CFR 820.100(a)(6).

j. The CAPA procedures must include requirements for: "Submitting relevant information on identified quality problems, as well as

corrective and preventive actions, for management review[.]" 21 CFR 820.100(a)(7).

k. All required CAPA activities, and their results, "shall be documented[.]" 21 CFR 820.100(b).

32. On information and belief, the Ethicon Defendants did not comply with one or more of the requirements of 21 CFR 820. Had they done so, Plaintiff would not have been injured by a defective Ethicon Stapler.

33. The EEA utilized on Plaintiff was not manufactured in accordance with its FDA and/or CAPA requirements, and in the failure to do so - Defendant's failed to exercise reasonable care, and/or acted with gross negligence.

34. These breaches of duty were a proximate caused Plaintiff's damages as described herein.

COUNT 2 – PRODUCTS LIABILITY: IMPLIED WARRANTY

35. Plaintiff incorporates the preceding allegations as if fully incorporated herein.

36. The EEA device produced and sold by Ethicon Defendants was not reasonably fit for the uses or purposes anticipated or reasonably foreseen by Ethicon Defendants when it left Ethicon Defendants control.

37. As a proximate result of the breach of implied warranty by Ethicon Defendants, Plaintiff was damaged as described herein.

COUNT 3 – PRODUCTS LIABILITY: EXPRESS WARRANTY

38. Plaintiff incorporates the preceding allegations as if fully incorporated herein.

39. As of, and prior to, July 3, 2016, Ethicon Defendants asserted in the "surgical stapling" portion of their product catalog: "Reliable tissue repair is a critical factor for all surgery. That's why Ethicon has worked with surgeons worldwide to develop and refine our surgical staplers and cutters. Our surgical stapling portfolio addresses the issues of tissue thickness, ***staple line security***, and tissue tension to provide you solutions that are designed to enhance control and ***patient safety***". *See 2016 Ethicon Product Catalog*, pp. 26–27, http://pdf.medicalexpo.com/pdf/ethicon/2016-ethicon-product-catalog/74984-154353-_27.html (emphasis added).

40. Plaintiff and her physicians relied on the representation or statement of express warranty as previously described.

41. As a proximate result of the breach of express warranty by Ethicon Defendants Plaintiff was damaged as described herein.

DAMAGES

42. Plaintiff incorporates the preceding allegations as if fully incorporated herein.

43. As a result of all the actions and omissions described herein; Plaintiff sustained serious and permanent injuries including, but not limited to, the following:

a. Past and future medical expenses;

b. Permanent disfigurement and scarring;

c. Pain and suffering;

d. Emotional distress;

e. Exemplary damages;

f. Interest, attorney fees and costs; and

g. Other miscellaneous damages.

WHEREFORE, PLAINTIFF, requests the Court to grant Judgement against Defendants in the amount to which Plaintiff is entitled, together with costs, interest and attorney fees, and such other and further relief as the court finds just equitable, and proper under the circumstances.

Respectfully Submitted,

OLIVER LAW GROUP P.C.

Date: September 30, 2021

/s/ Alyson Oliver

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JURY DEMAND

NOW COMES PLAINTIFF, BRENDA CRISP, by and through counsel OLIVER LAW GROUP, P.C., and demands a jury trial in this matter.

Respectfully Submitted,

OLIVER LAW GROUP P.C.

Date: September 30, 2021

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